No. 08/035,150, filed March 26, 1993, now issued as U.S. Patent No. 5,362,478, the contents of each of which are hereby incorporated by reference in their entirety.

IN THE CLAIMS

Please replace claims 1, 17, 30, 45, 58-70, 79-91, 98, 102, 104, 108, 110, 114, 116, 120, 122, 126, 137, 142, 156, 159, 160, and 163-171 with the amended forms thereof presented herein. The Appendix enclosed herewith explicitly illustrates the amendments to these claims. For the Examiner's convenience, the Appendix also includes unamended claims, marked as reiterated.

1. A unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about 3 hours.

17. A unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over an administration period no greater than about 3 hours.

30. A unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 40 mg/m^2 to about 800 mg/m^2 with a cycle time of no greater than about three weeks between administrations of said total dose.

45. A unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 with a cycle time of no greater than about three weeks between administrations of said total dose.

58. A unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said container comprises in the range of about 4 mg to about 822 mg of said taxane.

59. A unit dosage form according to claim 58, wherein said container comprises in the range of about 4 mg to about 13 mg of said taxane.

60. A unit dosage form according to claim 58, wherein said container comprises in the range of about 13 mg to about 30 mg of said taxane.

61. A unit dosage form according to claim 58, wherein said container comprises in the range of about 20 mg to about 69 mg of said taxane.

62. A unit dosage form according to claim 58, wherein said container comprises in the range of about 45 mg to about 69 mg of said taxane.

63. A unit dosage form according to claim 58, wherein said container comprises in the range of about 69 mg to about 90 mg of said taxane.

64. A unit dosage form according to claim 58, wherein said container comprises in the range of about 69 mg to about 103 mg of said taxane.

65. A unit dosage form according to claim 58, wherein said container comprises in the range of about 103 mg to about 120 mg of said taxane.

66. A unit dosage form according to claim 58, wherein said container comprises in the range of about 103 mg to about 148 mg of said taxane.

67. A unit dosage form according to claim 58, wherein said container comprises in the range of about 120 mg to about 367 mg of said taxane.

68. A unit dosage form according to claim 58, wherein said container comprises in the range of about 148.1 mg to about 367 mg of said taxane.

69. A unit dosage form according to claim 58, wherein said container comprises in the range of about 367 mg to about 548 mg of said taxane.

70. A unit dosage form according to claim 58, wherein said container comprises in the range of about 367 mg to about 822 mg of said taxane.

79. A unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said container comprises a unit dose in the range of about 4 mg to about 822 mg of said docetaxel.

80. A unit dosage form according to claim 79, wherein said container comprises in the range of about 4 mg to about 13 mg of said docetaxel.

81. A unit dosage form according to claim 79, wherein said container comprises in the range of about 13 mg to about 30 mg of said docetaxel.

82. A unit dosage form according to claim 79, wherein said container comprises in the range of about 20 mg to about 69 mg of said docetaxel.

83. A unit dosage form according to claim 79, wherein said container comprises in the range of about 45 mg to about 69 mg of said docetaxel.

84. A unit dosage form according to claim 79, wherein said container comprises in the range of about 69 mg to about 90 mg of said docetaxel.

85. A unit dosage form according to claim 79, wherein said container comprises in the range of about 69 mg to about 103 mg of said docetaxel.

86. A unit dosage form according to claim 79, wherein said container comprises in the range of about 103 mg to about 120 mg of said docetaxel.

87. A unit dosage form according to claim 79, wherein said container comprises in the range of about 103 mg to about 148 mg of said docetaxel.

88. A unit dosage form according to claim 79, wherein said container comprises in the range of about 120 mg to about 367 mg of said docetaxel.

89. A unit dosage form according to claim 79, wherein said container comprises in the range of about 148 mg to about 367 mg of said docetaxel.

90. A unit dosage form according to claim 79, wherein said container comprises in the range of about 367 mg to about 548 mg of said docetaxel.

91. A unit dosage form according to claim 79, wherein said container comprises in the range of about 367 mg to about 822 mg of said docetaxel.

98. A unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

102. A unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said docetaxel remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

104. A unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said taxane.

108. A unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said docetaxel.

110. A unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of primary tumors.

114. A unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of primary tumors.

116. A unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of metastatic tumors.

120. A unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of metastatic tumors.

122. A unit dosage form comprising a vessel containing a quantity of a formulation of taxane sufficient to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said formulation does not leach plasticizer from administration devices used to administer said unit dosage formulation.

126. A unit dosage form comprising a container containing a quantity of a formulation of docetaxel sufficient to provide for administration to a subject a total dose of docetaxel in the range

of about 30 mg/m^2 to about 1000 mg/m^2, wherein said formulation does not leach plasticizer from administration devices used to administer said unit dosage formulation.

137. A unit dosage form comprising a container containing a sufficient quantity of taxane to allow systemic administration to a subject, employing a standard intravenous infusion set, of a total dose in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane.

142. A unit dosage form comprising a container containing a sufficient quantity of docetaxel to allow systemic administration to a subject, employing a standard intravenous infusion set, of a total dose in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said docetaxel.

156. A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

159. A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said docetaxel remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

160. A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said taxane.

163. A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a container containing a sufficient quantity

of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said docetaxel.

164. A method for treatment of primary tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

165. A method for treatment of primary tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

166. A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

167. A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

168. A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane does not leach plasticizer from administration devices used to administer said unit dosage formulation.

169. A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said docetaxel does not leach plasticizer from administration devices used to administer said unit dosage formulation.

170. A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.

171. A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.

REMARKS

In accordance with the present invention, there are provided unit dosage forms of taxanes (e.g., paclitaxel, docetaxel, and the like), formulations thereof, and methods for use thereof. Invention unit dosage forms allow systemic administration to a human subject in need thereof at dose levels and over administration periods and/or treatment cycles not previously possible. Due to the larger amounts of taxanes provided by invention unit dosage forms, the present invention offers both markedly improved therapeutic benefits and dramatically reduced administration periods, thereby alleviating discomfort experienced by a subject in need thereof.

By the present communication, claims 1, 17, 30, 45, 58-70, 79-91, 98, 102, 104, 108, 110, 114, 116, 120, 122, 126, 137, 142, 156, 159, 160, and 163-171 have been amended to define Applicants' invention with greater particularity. No new matter has been introduced as the